OFFICE OF SPECIAL MASTERS

December 15, 2005

ORDER TO SHOW CAUSE¹

Attached to this Order to Show Cause are two prior Orders of the undersigned. The first Order, dated August 21, 2001, orders petitioner to explain discrepancies between petitioner's affidavits and the contemporaneous medical records by November 5, 2001 (over five years ago).

¹ Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

Petitioner never responded. The second attachment is the undersigned's Preliminary Findings, dated January 25, 2002 (almost four years ago), that petitioner cannot prevail in this case because her son's symptoms occurred two months after his second hepatitis B vaccination. Petitioner has continued to remain silent about this deficiency in her case.

Dr. Campbell's conclusions are based on histories petitioner gave him that conflict markedly with the contemporary medical records and therefore are not credible. Dr. Scheibner is not a medical doctor and her opinion is irrelevant and inadmissible.

Petitioner's counsel's entitlement to fees and costs is based on the undersigned's finding that "the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought." 42 U.S.C. § 300aa-15(d)(1). Petitioner has continued to file thousands of pages in medical records over the four and five years since the Orders described above were filed as if records noting the tragically ill condition of Jonathan Carrington resolved the deficiency between Mrs. Carrington's assertions in the context of litigation (and congressional testimony) and the contemporaneous medical records which note the histories she gave at the time Jonathan became ill. This does not manifest good faith. Instead, it manifests a deliberate ignoring of the undersigned's concerns about the merits of this case.

It is true that on February 24, 2003, at petitioner's counsel's request, the undersigned stayed proceedings in numerous cases including this one because petitioner's counsel could not handle them all. Yet, petitioner's counsel still is able to file thousands of pages in this particular case, which means that there is some activity proceeding, but not a focus on the fatal conflict between petitioner's assertions and the contemporaneous medical records. This cannot go on any

longer. Petitioner is ORDERED TO SHO	OW CAUSE why this case should not be dismissed by
January 27, 2006.	
IT IS SO ORDERED.	
DATE	Laura D. Millman Special Master

ATTACHMENT ONE

OFFICE OF SPECIAL MASTERS

August 21, 2001

ORDER

The undersigned has reviewed the file, although petitioner has not as yet filed the hard copies of the medical records and expert reports. Apparently, petitioner alleges that Jonathan Carrington's first and second hepatitis B vaccinations caused him to suffer an aneurysm two months after his second hepatitis B vaccination.

An aneurysm has been described as follows:

Intracerebral aneurysms can result from trauma, infection, or neoplastic disease. Most aneurysms, however, result from a developmental abnormality of the inside lining or intima of an artery with abnormal thinning of the vessel at the site of origin. It appears there may be a genetic predisposition to the development of intracerebral aneurysms; the existence in some families runs as high as 10%, approximately 10 times higher than that found in the general population. There

are several other causes of intracerebral aneurysms. For example, they can result from infected embolic material from a bacterial infection on one of the heart valves being deposited on one of the arteries in the brain(mycotic aneuryms). Gary L. Bernardini, M.D., Ph.D., Department of Neurology and Neuroscience, The New York Hospital/Cornell University Medical Center, 1300 York Avenue, NY, NY 10021 (www.columbia.edu/~mdt1/cerebfaq.txt).

Petitioner's theory seems to be that Jonathan's screaming constantly since his first hepatitis B vaccination caused his aneurysm. The undersigned has read respondent's report which appears to indicate that petitioner did not give a history of continual crying since the first hepatitis B vaccination. Nevertheless, petitioner has provided no medical substantiation for her allegation. She has submitted a letter from Dr. Viera Scheibner (it is unclear if Dr. Scheibner is a medical doctor) stating that screaming did not cause Jonathan's aneurysm. Rather, Jonathan's aneurysm caused his screaming. Contrary to Dr. Scheibner's letter is Dr. Andrew W. Campbell's letter that screaming could cause the rupture of an aneurysm. But Dr. Campbell does not state that it did so in this case, nor does he give a basis for his opinion. Petitioner submitted a letter from Dr. R.A. Neubauer whose specialty is unknown, but who opines that Jonathan had anoxic toxic encephalopathy directly related to hepatitis B vaccine. However, Dr. Neubauer does not give a basis for his opinion. The allegations do not support an encephalopathy until after Jonathan experienced an aneurysm, and Dr. Neubauer says nothing about the aneurysm.

The undersigned ORDERS petitioner to submit affidavits and/or reports that will clarify and rectify these deficiencies, and hard copies of the medical records, by November 5, 2001.

IT IS SO ORDERED.		
DATE	Laura D. Millman Special Master	

ATTACHMENT TWO

OFFICE OF SPECIAL MASTERS

January 25, 2002

PRELIMINARY FINDINGS

On August 21, 2001, the undersigned issued an Order requiring petitioner to cure deficiencies in the medical expert reports submitted by November 5, 2001. Petitioner never responded to this Order. In the meantime, the undersigned has reviewed the file and is ready to make **Preliminary Findings**:

(1) Dr. Campbell's conclusions are based on erroneous assumptions that Jonathan had continuous, violent crying from the time of his first hepatitis B vaccination straight through and after the second hepatitis B vaccination. The undersigned rejects Dr. Campbell's conclusions.

(2) Dr. Viera Scheibner, whose report petitioner also submitted, is not a medical doctor but a Ph.D. in natural sciences.² This case does not concern geology. Dr. Scheibner's opinion about the medical effects of vaccination is irrelevant to the undersigned. The undersigned orders Dr. Scheibner's opinion (P. Ex. 11) struck from evidence. <u>Domeny v. Secretary, HHS</u>, No. 94-1086V, 1999 WL 199059 (Fed. Cl. Spec. Mstr. March 15, 1999), <u>aff'd</u> (Fed. Cl. May 25, 1999) (unpublished), <u>aff'd</u>, No. 99-5130 (Fed. Cir. April 10, 2000) (per curiam) (unpublished) (proffer of dentist's testimony for diagnosis of a neuropathy rejected).

Statement of the Case

Tammy Carrington, Jonathan's mother, testified before Congress on June 15, 1999 that the change in Jonathan before and after his first hepatitis B vaccination on August 3, 1997, was like "night and day." Attachment to P. Status Report, etc., filed Nov. 1, 2001, p. 2. Within four hours of his first vaccination, she testified that he began crying which turned quickly into screaming. He was inconsolable. She and her husband called the staff of the hospital where

² Petitioner did not submit Dr. Scheibner's C.V., but an abridged version is available on the internet: www.survivalofthespecies.com/VieraScheibnerCV.htm. She received her doctorate in natural sciences in Bratislava in 1964 where she was employed in the Department of Geology and Paleontology from 1958-68. She moved to Australia in 1968 and was employed as a micropaleontologist in the Department of Mineral Resources by the Geological Survey of New South Wales. From 1968-87, she studied cretaceous and permian foraminifera of the Great Australian Basin and the Carnarvon Basin. In 1985, she began studying breathing monitors for babies, which led to her interest in SIDS deaths and thence to immunizations. Her view, as expressed in congressional testimony on June 6, 1999, is that vaccines do not prevent disease and we do not need them. Specifically she testified that vaccines did not eradicate polio. Rather doctors rediagnosed polio as viral or aseptic meningitis, which is why it seems eradicated. See www.whale.to/vaccines/scheibner8.html. Her anti-vaccine website has won the Anus Maximus Award for 1999 in Australia. See www.ratbags.com/rsole/comment/scheibner.htm. Dr. Scheibner has the dubious distinction of being awarded the Bent Spoon Award for 1997 in Australia for her role as "the perpetrator of the most preposterous piece of paranormal or pseudoscientific piffle." See both http://www.skeptics.com.au/features/spoon/bs-win97.htm and www.wysiwyg://16/http://www.geocities....on/fearmongers/viera scheibner.htm

Jonathan was born many times and they told her to let him cry for 7-10 minutes to see if he would stop. He did not stop except if he were nursing. "His screams were blood curdling, top-of-the-lungs crying." Mrs. Carrington testified that Jonathan's screams continued 90% of his waking hours for weeks and months. <u>Id</u>.

He had his second hepatitis B vaccination on October 13, 1997³ and the pediatrician diagnosed Jonathan with colic and said he would grow out of it. Mrs. Carrington thought she would lose her mind from the constant, inconsolable crying. She complains she could not take Jonathan into public because of the crying and she thought all children were this way. Id. at 2-3.

On December 11, 1997, two months after Jonathan's second hepatitis B vaccination, he had an aneurysm with disastrous consequences.

In a VAERS report that Mrs. Carrington filled out on January 6, 2000, she writes:

My son began screaming a high pitched, blood curdling, top of his lungs scream within 4 hours of receiving his 1st Hep B vaccine when he was 3 days old. He didn't cry like this before his shot. He then never slept more than 15-40 minutes at a time and never more than 4 hours in a 24 hour period. He <u>screamed</u> 90% of his waking hours and was inconsolable. He was constipated, irritable, agitated and screamed like he was in pain–panicked. He received his 2nd Hep B at 2 months of age and screaming got worse. He also became constipated, agitated, irritable, got cradle cap w/ alopecia after 1st vaccine, worsened by 2nd vax." [Emphasis in the original.]

P. Ex. 10, p. 4.

The contemporaneous medical records, however, show that in the ten pediatric records between Jonathan's birth and his aneurysm, Mrs. Carrington did not once complain about Jonathan's blood-curdling screams or even crying. Moreover, after his colic was successfully

³ The petition, at paragraph 3, states that Jonathan's second hepatitis B vaccination was on October 10, 1997, but P. Ex. 3, p. 25 notes it was October 13, 1997.

treated, he was sleeping 10-11 hours through the night. The pediatrician, Dr. Fidone, noted that Jonathan was well and his behavior and activity good..

These are the pediatric entries between 8/4/97 until 12/11/97 when Jonathan had his aneurysm:

8/4/97 (one day after the first hepatitis B vaccination) - blood in urine, not sleeping. Ex. 3, p. 28.

8/5/97 - extensive discussion with mother about breast feeding and daily bowel movements. Ex. 3, p. 27.

8/11/97 - poor stool output, tight rectal sphincter. At 4:30 p.m.,. removed vaseline gauze, applied gel foam to underside, no bleeding, instructed parents. Ex. 3, p. 27.

8/14/97 - constipated, breast feeding well, milk good, poor sleeping, **good behavior**, good activity, stools starting to soften, colic symptoms slightly improved, good weight gain, tight rectal sphincter. Ex. 3, p. 27.

8/18/97 - rectal dilation, had bowel movement last night and this afternoon. Ex. 3, p. 26. 8/25/97 - no show. Ex. 3, p. 26.

9/15/97 - Micronor birth control - okay to breast feed? No problems according to PDR. Ex. 3, p. 26.

9/19/97 - spitting up after breast feeding, no temperatures, gets fussy and wiggly, she takes him off breast and tries to burp him, he spits up. Rx: Zantac. Ex. 3, p. 26.

9/20/97 - weight check for Zantac. Ex. 3, p. 26.

10/13/97 - breast on demand, will sleep 10-11 hours through night, well, second Hep B. Ex. 3, p. 25. (Compare this to Mrs. Carrington's claim that he never slept more than 4 hours.)

12/11/97 - two teeth, maybe cutting more, **high-pitched screaming and shaking 20-25 minutes at a time this a.m. and last night**, extends legs, rubbing eye x 10 day, vomiting x 1 day, tired, pale, anterior fontanel pulsatile, appetite decreased x 1 day, **crying x 3 days**, limp.

Ex. 3, p. 25.

Clearly, from the medical records, Jonathan's screaming began on December 8, 1997, according to the history that Mrs. Carrington gave to her pediatrician, Dr. Fidone. She went often enough to the doctor to have told him everything concerning Jonathan. The medical records show that he had trouble moving his bowels in the beginning, which caused poor sleeping. But even with colic, he had good behavior, according to the note of August 14, 1997. This is during the time when he was supposed to be screaming his head off 90% of the time.

Once Jonathan was brought to Schumpert Health System hospital, Mrs. Carrington had the opportunity to give a history to a succession of doctors. To none of them did she recount a four and one-half month duration of blood-curdling cries. Specifically, in the Transport and Admit Note of December 11, 1997, Mrs. Carrington "reports that child was well until this am when he developed irritability" associated with two episodes of non-bloody, no bilious emesis. Dr. Fidone wrote this note. He also records that Jonathan's immunizations were up to date. If Mrs. Carrington could mention his immunizations, she could also mention how Jonathan's behavior changed radically after his first hepatitis B vaccination, but she did not. Ex. 12, p. 98.

Jonathan was discharged from the hospital on January 13, 1998. In his discharge summary, Dr. Giao Ngoc Do states that Mrs. Carrington reported that Jonathan was crying more than normally on the day of admission and refused to nurse. She brought him to see Dr. Fidone

at 11:00 a.m. and he sent him for blood tests. At 2:00 p.m., Jonathan became more irritable, lethargic, and nauseated. Ex. 12, p. 36.

Dr. James Kim, a neurologist, consulted on the case on December 12, 1997, and noted that Jonathan was fine until admission when he was noted to be irritable and cranky. His past medical history was unremarkable. He had no neonatal complications. His developmental milestones were normal for age. He had no preceding illness or fever. Ex. 7, p. 39.

Dr. David Cavanaugh also consulted on the case on December 12, 1997. He wrote a history that Jonathan was doing well until the night before admission when he was perhaps a little more irritable. Dr. Cavanaugh spoke to Jonathan's parents who reiterated the history that there was no trauma and Jonathan had no other problems within 24 hours of the aneurysm. His past medical history was unremarkable for any problems in the postnatal period. Ex. 7, p. 43.

It is frankly impossible for Jonathan to have had four and one-half months of blood-curdling screams from the time of his first hepatitis B vaccination until his aneurysm, but Mrs. Carrington and her husband failed to tell Dr. Fidone during that time and furthermore failed to tell four other physicians at the hospital after Jonathan had his aneurysm that he had been screaming 90 percent of the time since the day after he was born.

Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. <u>United States v. United States Gypsum Co.</u>, 333 U.S. 364, 396 (1948); <u>Burns v. Secretary, HHS</u>, 3 F.3d 415 (Fed. Cir. 1993); <u>Ware v. Secretary, HHS</u>, 28 Fed. Cl. 716, 719 (1993); <u>Estate of Arrowood v. Secretary, HHS</u>, 28 Fed. Cl. 453 (1993); <u>Murphy v. Secretary, HHS</u>, 23 Cl. Ct. 726, 733 (1991), <u>aff'd</u>, 968 F.2d 1226 (Fed. Cir.), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992); Montgomery Coca-Cola

<u>Bottling Co. v. United States</u>, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Perhaps, Mrs. Carrington has confused the screaming Jonathan had a few days before his aneurysm and after it with his neonatal history. For instance, in a discharge summary dated April 8, 1998, Dr. Do states that approximately two weeks after Jonathan's right subdural drain (after the aneurysm) was removed, he developed a high-pitched crying spell with some abnormal jerking movements. He continued having high-pitched crying episodes throughout the day which did not resolve with any medications. Finally, he was placed on Morphine and Ativan for his pain. Ex. 13, p. 6. Jonathan continued to have crying episodes which were uncontrollable. He responded only to a combination of Morphine and Ativan for his crying episodes. He appeared to be irritable at times for no apparent reason. Id.

Jonathan's case is tragic, but the facts indisputably do not show violent screaming until a few days before his aneurysm. In order for petitioner to present a prima facie case, she needs expert medical evidence proving that Jonathan's second hepatitis B vaccination caused his aneurysm two months later without intervening symptoms. In the alternative, she needs expert medical evidence proving that Jonathan's first hepatitis B vaccination caused his aneurysm four

and one-half months later or in combination with the second hepatitis B vaccination two months before onset of the aneurysm.

The court ORDERS that P. Ex. 11 (Dr. Scheibner's report) be stricken.

The undersigned is aware that petitioner's counsel is attempting to obtain expert medical support for various allegations relating to hepatitis B vaccination in numerous cases. The undersigned will set up a telephonic status conference with the parties for some time after mid-March 2002. At this moment, petitioner has not set forth a prima facie case of causation in fact.

IT IS SO ORDERED.	
DATE	Laura D. Millman Special Master